Amendments to the Specification:

Please amend the paragraphs of the specification as indicated:

[0002] The present ~~invention~~ disclosure relates to neurostimulator implant devices, and more particularly to a system and method that uses multi-electrode stimulation provided by a neurostimulator implant device to elicit electrically-evoked compound action potentials. Such an evoked compound action potential (ECAP) provides valuable objective feedback information useful in setting the stimulation parameters associated with the neurostimulator implant device.

[0003] Traditional methods used to elicit the electrically-evoked compound action potential, or ECAP, deliver stimulation to a single electrode contact. There are cases where such application of a stimulus to a single electrode contact do not evoke a suitable action potential. The present ~~invention~~ disclosure provides an improved system and method for obtaining the ECAP through application of the stimulus to multiple electrodes. The present ~~invention~~ disclosure may be used in many different kinds of neurostimulator devices, but will be described in terms of a cochlear implant device.

[0013] Typically, when the fitting systems described in the '629 or '247 patents are employed for multichannel stimulation systems, or when equivalent or similar fitting systems are employed, it is necessary to use directly measured threshold values and/or thresholds derived from the measurement of psycophysically-determined pseudo-comfort levels. That is, for each channel of the multichannel system, a minimum threshold level is measured, typically referred to as a "T" level, which represents the ~~minium~~ minimum stimulation current which when applied to a given electrode associated with the channel produces a sensed perception of sound at least 50% of the time. In a similar manner, an "M" level is determined for each channel, which represents a stimulation current which when applied to the given electrode produces a sensed perception of sound that is moderately loud, or comfortably loud, but not so loud that the perceived sound is uncomfortable. These "T" and "M" levels are then used by the fitting software in order to properly map sensed sound to stimulation current levels that can be perceived by the patient as sound.

[0022] The present ~~invention~~ specification addresses the above and other needs by spatially spreading the excitation pattern in the cochlea (or other target neural tissue) by either: (1) rapid sequential stimulation of a small group of electrodes, or (2) simultaneously stimulating a small group of electrodes. Such multi-electrode stimulation advantageously stimulates a greater number of neurons in a synchronous manner, thereby increasing the amplitude of the extra-cellular voltage fluctuation and facilitating its recording.

[0023] The present ~~invention~~ specification is intended for use with multichannel neurostimulation systems, e.g., multichannel cochlear stimulation systems, wherein stimuli can be applied simultaneously to multiple channels, or can be applied sequentially to multiple channels at a sufficiently fast rate so as to provide a synchronous response.

[0024] ~~In accordance with one aspect of the invention~~ For example, electrical stimuli are applied simultaneously (or sequentially at a rapid rate) on selected small groups of electrodes while monitoring the ECAP on a nearby electrode. The presence of an observable ECAP advantageously validates operation of the implant device at a time when the patient may be unconscious or otherwise unable to provide subjective feedback.

[0025] In ~~accordance with another aspect of the invention~~ another example, the magnitude of the observed ECAP is recorded (or otherwise observed, or saved) as a function of the amplitude of the applied stimulus. From this data, an appropriate (safe, efficacious and comfortable) threshold level can be obtained which may be used as the initial setting of the stimulation parameters of the neurostimulation device, or which may be used to guide or steer the setting of the stimulation parameters of the neurostimulation device.

[0026] In ~~accordance with yet another aspect of the invention~~ another example, stimulus levels are progressively set in bands, e.g., groups of electrodes or channels. By progressively setting threshold levels in bands, either overlapping or non-overlapping, a set of data is obtained (which set of data may be smoothed, as required, using, e.g., a 3-point weighted average, b-spleen interpolation, or other known smoothing techniques) that provides a basis for

setting appropriate (safe, efficacious and comfortable) stimulation parameters for each individual electrode contact during operation of the neurostimulator device.

[0027] ~~It is thus a feature of the present invention to provide~~ Thus, the present specification describes an improved system and method of fitting a neurostimulator device by measuring the ECAP of the patient through application of multi-band (i.e., multi-electrode contact) stimulation in order to better determine appropriate intensity threshold levels used by the implant system during its operation.

[0028] ~~It is a further feature of the invention to provide~~ The present specification further describes such an improved system and method of fitting that does not require subjective feedback from the patient during the fitting procedure.

[0029] ~~It is an additional feature of the invention to provide~~ The present specification also describes an improved technique for evoking a compound action potential for the purpose of validating proper operation of the implant device at a time shortly after the device is implanted at a time when the patient may still be under the influence of an anesthesia, and hence unconscious.

[0034] FIG. 3B conceptually illustrates simultaneous application of an electrical stimulus on multiple electrode contacts in order to evoke a compound action potential ~~in accordance with the present invention~~;

[0035] FIG. 3C conceptually illustrates rapid sequential application of an electrical stimulus on multiple electrode contacts in order to evoke a compound action potential ~~in accordance with the present invention~~;

[0041] FIG. 1 shows a current stimulation waveform (I) and a corresponding evoked compound action potential (ECAP). FIG. 1 defines the stimulation rate (1/T), amplitude (A) and biphasic pulse width (PW) associated with the current stimulation waveform. FIG. 2 also illustrates a typical ECAP waveform that is evoked in response to the applied current stimulation

waveform. Such ECAP waveform is typically characterized by three humps, or peaks, labeled P1, N1, and P2. The first peak P1 is, as illustrated in FIG. 1, a positive peak and is often difficult to measure, as it may be swamped out by other electrical activity. The second peak N1, as illustrated in FIG. 1, is a negative peak. The third peak P2, as illustrated in FIG. 1, is another positive peak. While numerous parameters associated with the ECAP waveform may be monitored or measured, a preferred parameter is the peak-to-peak amplitude between the peaks N1 and P2, labeled V_{PP} in FIG. 1. It should be noted that in some instances, depending upon the polarity of the leads used to monitor the ECAP waveform, the waveform shown in FIG. 1 may be inverted, i.e., with P1 and P2 being negative peaks, and N1 being a positive peak. Such inversion does not significantly alter the peak-to-peak value V_{PP} used ~~by the present invention~~ herein as a measure of the ECAP amplitude.

[0042] FIG. 2A shows a representative neurostimulation system, i.e., a cochlear stimulation system. The ~~present invention will be~~ principles described herein will be described in terms of ~~its use within~~ a cochlear stimulation system. However, it is to be understood that ~~the invention~~ these principles may be used with any type of multichannel neurostimulation system.

[0049] The speech processing strategy is used, *inter alia*, to condition the magnitude and polarity of the stimulation current applied to the implanted electrodes of the electrode array 48. Such speech processing strategy involves defining a pattern of stimulation waveforms that are to be applied to the electrodes as controlled electrical currents. ~~In accordance with the present invention~~ As described herein, during the fitting process, a strategy is used which stimulates selected groups of the implanted electrodes either simultaneously or sequentially at a high rate. Here, "high rate" means any rate sufficiently fast so as to evoke a synchronized neural response from the neurons in the surrounding target tissue. In general, such sequential stimulation at a "high rate" has the same effect as would a simultaneous stimulation. For many patients, a rate greater than about 5 KHz would qualify as a "high rate" stimulation. During such stimulation, an adjacent electrode contact within the electrode array is monitored for the occurrence of an ECAP in response to the applied stimulation.

[0050] As indicated, the types of stimulation patterns applied to the electrode groups may be conveniently categorized as: (1) simultaneous stimulation patterns, or (2) non-simultaneous stimulation patterns. Simultaneous stimulation patterns may be "fully" simultaneous or partially simultaneous. A fully simultaneous stimulation pattern is one wherein stimulation currents, either analog or pulsitile, are applied to the electrodes of all of the available channels at the same time. A partially simultaneous stimulation pattern is one wherein stimulation currents, either analog or pulsitile, are applied to the electrodes of two or more channels, but not necessarily all of the channels, at the same time. Examples of each type of [[are]] strategy are given in U.S. Patent 6,289,247, incorporated herein by reference. A non-simultaneous stimulation pattern applies stimulation currents to electrodes in a sequential manner, e.g., only one electrode pair at a time. However, the rate of stimulation applied to different electrode pairs may be sufficiently fast so that the stimulation has the same affect as though it were applied to all of the selected electrode pairs simultaneously.

[0052] Current pulses applied in pulsitile stimulation patterns are generally biphasic pulses, as shown in FIG. 1, but may also be multiphasic pulses, applied to the electrodes of each channel. The biphasic/multiphasic pulse has a magnitude (e.g., amplitude “A” and/or duration “PW”) that varies as a function of the sensed acoustic signal or other source of modulation. (A "biphasic" pulse is generally considered as two pulses: a first pulse of one polarity having a specified magnitude, followed immediately, or after a very short delay, by a second pulse of the opposite polarity having the same total charge, which charge is the product of stimulus current times duration of each pulse or phase.) For multichannel cochlear stimulators of the type ~~used with the present invention~~ described herein, it is common to apply a high rate biphasic stimulation pulse train to each of the pairs of electrodes in a selected group of electrodes in accordance with a selected strategy, and modulate the pulse amplitude of the pulse train as a function of information contained within the sensed acoustic signal, or the received auxiliary input signal.

[0061] With the preceding as background information relative to a typical cochlear implant system, which is representative of a neurostimulation system, the ~~present invention provides~~ specification will now fully describe an improved method of fitting the neurostimulation

system, i.e., a cochlear implant system, to a patient by applying stimuli to multiple bands of electrodes, e.g., multiple groups of electrodes, while monitoring the ECAP that such stimuli elicits. This is done for the purpose of helping to initially set program parameters, e.g., the amplitude of the stimulation current, so that when the implant device (e.g., the implantable cochlear stimulator) is first turned on, the intensity of the stimulation will be sufficiently strong so as to evoke a desired response, but not too strong so as to make the stimulation uncomfortable or painful for the patient.

[0062] In ~~accordance with one important aspect of the invention~~ one example, a stimulus is applied to multiple electrode contacts either simultaneously, or sequentially at a fast rate, so as to produce a recordable ECAP. This process is conceptually illustrated in FIGS. 3A, 3B and 3C, which figures show multiple spaced-apart electrode contacts E1, E2, E3 and E4 in contact with, or near, body tissue 200 that is to be stimulated. In FIG. 3A, a stimulus current pulse is applied to electrode E2 by current source 202, while electrode E3 is used as a "sensor" to determine if the applied stimulus produces any neural response in the tissue. Such neural response would be indicated, e.g., by sensing the presence of an evoked compound action potential, or ECAP, on electrode E3. Such ECAP, if present, is sensed through sense amplifier 204 as waveform 206.

[0064] To overcome the limitations associated with use of a single electrode contact, as shown in FIG. 3A, the present ~~invention~~ specification describes the application of ~~applies~~ a current stimulus pulse from a current source 202 to multiple electrode contacts simultaneously, as shown in FIG. 3B. That is, as shown conceptually in FIG. 3B, the current pulse from current source 202 is applied to electrode contacts E1, E2 and E3 simultaneously, while electrode contact E4 is used as a sense electrode. The electric fields 208 that propagate into the surrounding tissue 200 from each of the electrode contacts E1, E2, and E3 affect a much larger tissue area, and are thus able to capture more neural cells, and thereby more easily produce the desired evoked response. The desired evoked response, or ECAP, is sensed through sense amplifier 204 as ECAP waveform 206'.

[0065] As an alternative to the simultaneous approach depicted in FIG. 3B, a ~~repaid~~ rapid sequential stimulation may also be used, as conceptually illustrated in FIG. 3C. As seen in FIG. 3C, a stimulus current pulse from current source 202 is applied through switch 210 in sequence to electrodes E1, E2, and E3. That is, electrode E1 first receives the pulse, followed a short time thereafter by electrode E2, and followed a short time thereafter by electrode E3. This sequencing may repeat itself, as needed. In order for the sequential approach of FIG. 3C to work it is necessary that the sequencing be done at a high (or rapid) rate. A "high rate", as previously indicated, means a rate sufficiently fast so as to produce a synchronized evoked response from the surrounding tissue. A representative high rate for stimulating cochlear tissue might be, e.g., 5KHz or faster. Conceptually, this means that the electric field 208 that propagates out from each electrode E1, E2, E3, as each is stimulated in sequence with a stimulus pulse (which electric field has a lingering affect on the tissue 200 in which it propagates), has sufficient overlap with the adjoining electric fields so as to affect a larger tissue area, thereby capturing more neural cells, and thereby more easily producing the desired evoked response. The evoked response 206" is sensed through sense amplifier 204, which is connected to the "sense" electrode E4.

[0066] Thus it is seen that one ~~aspect of the present invention~~ example of the techniques described herein involves applying a stimulus pulse to multiple electrodes, either simultaneously (as represented in FIG. 3B) or sequentially at a fast rate (as represented in FIG. 3C), in order to more effectively elicit a desired evoked compound action potential, or ECAP, from the targeted tissue.

[0067] Next, a description is provided of how such an elicited ECAP is used ~~by the invention~~ to more effectively program, or "fit", a neurostimulator device to a patient. Typically, when a fitting system, such as the fitting system described in the previously referenced '629 or '247 patents, is employed for multichannel stimulation systems, or when equivalent or similar fitting systems are employed, it is necessary to use directly measured threshold values and/or thresholds derived from the measurement of psycophysically-determined pseudo-comfort levels. That is, for each channel of the multichannel cochlear stimulation system, a minimum threshold level is measured, typically referred to as a "T" level, which represents the ~~minium~~

minimum stimulation current which when applied to a given electrode associated with the channel produces a sensed perception of sound at least 50% of the time. In a similar manner, an "M" level is determined for each channel, which represents a stimulation current which when applied to the given electrode produces a sensed perception of sound that is moderately loud, or comfortably loud, but not so loud that the perceived sound is uncomfortable. These "T" and "M" levels are then used by the fitting software in order to properly map sensed sound to stimulation current levels that can be perceived by the patient as sound.

[0069] Additionally, when fitting a patient with a cochlear implant, or other neurostimulation device, it is necessary and desirable to initially program the device with stimulation parameters that, when the device is first turned on, will not damage or be painful to the patient. Generally, this has required initially programming the device with very low stimulation levels, and then gradually and painstakingly increasing these levels until such time as the patient can just begin to perceive such stimulation, and going on from there. Again, such process is extremely time consuming and laborious. The ~~present invention~~ techniques described in this specification advantageously ~~shortens~~ shorten this process by providing a technique or tool whereby when the neurostimulation device is first implanted in the patient, and when the patient is still under the influence of an anesthesia, the surgeon and medical personnel in the operating room (OR), through use of multi-electrode stimulation to elicit an ECAP as explained above, can quickly ascertain appropriate threshold levels that can be initially programmed into the implant device for use by the device when it is first turned on. (The “turning on” of the implant device may not occur until several weeks after the surgery.) Moreover, in the process of obtaining these initial threshold levels, the proper operation of the implant device can be verified while the patient is still in the OR before the implant site is surgically closed.

[0074] Next, with reference to FIG. 5, a flow chart is shown that illustrates ~~the method of the invention~~ one example method of using the techniques described herein, wherein the main steps of the invention are identified in boxes or blocks that interconnect to define a flow or sequence of steps. As seen in FIG. 5, the method begins by defining a first group of electrodes that are to receive stimuli (block 300) for the purpose of eliciting an ECAP. Once such group of

electrodes is defined, the next step is to define an initial intensity level for the stimuli (block 302). Once the electrode group is defined, and the intensity level of the stimuli is defined, electrical stimuli of the defined intensity (amplitude) are simultaneously applied to the defined group of electrodes (block 304). Here, it should be noted that "simultaneous" is as defined previously. Simultaneous means that the stimuli are applied at the same time to all electrodes, *or* that the stimuli are applied sequentially to the electrodes within the group at a sufficiently fast rate to elicit a synchronous response from the targeted tissue.

[0086] The algorithm ~~of the invention~~ may be carried out while generating input/output (I/O) data in the OR on all electrodes. More particularly, the ~~invention teaches~~ techniques described herein include obtaining such data for groups of electrodes, e.g., four electrodes at one time, rather than obtaining data on individual electrodes. However, the group size of the number of electrodes in the group may be selected to be as small as one in the event data is desired from only a single electrode. The I/O data is obtained for a range of intensities (current stimulation pulses of different amplitudes and/or pulse widths), and is then plotted to allow tNRI data to be ascertained for each electrode.

[0087] The program ~~that carries out the invention~~ described is able to save or recall and repeat measurements. Moreover, the user can pause without losing data in order to adjust parameter values, e.g., step sizes and averages. Additionally, the user can view a real-time display of the ECAP waveforms during data collection. After data collection, the user can view single traces, an I/O plot, and computed tNRI values. The user is further allowed to reject single traces. Further, the user can run the program that carries out the invention in both a manual and automated (macro) operation mode.

[0089] By selecting a first amplitude for the stimulus current using the up arrow 406, a first ECAP waveform 410a is obtained. The amplitude of this waveform 410a can then be measured. By increasing the amplitude of the stimulus current, a second ECAP waveform 410b is obtained. The amplitude of the ECAP waveform 410b can also be measured. Similarly, by increasing the amplitude of the stimulus current to different levels, additional ECAP waveforms 410c and 410d [[is]] are obtained, each having an amplitude that can be measured. Thus, in

the manner described, four ECAP data points are obtained, each point having a stimulus current amplitude and an ECAP amplitude associated therewith.

[0090] FIG. 6B illustrates what happens when the "options" button 404 is selected. As seen in FIG. 6B, such action causes another window 412 to appear in the center of the screen that contains six options that may be further selected. One of the six options that may be selected is "Manual Plot". When the "Manual Plot" option is selected, a screen as shown in FIG. 6C appears. This screen contains an "EP vs. Stim Level" area 414 whereon [[the]] a plot may be made of the ECAP data points for the particular electrode group from which the ECAP data was obtained. From the plot, or from an extrapolation of the plot, a threshold line "t" may be established. Where the plot of EP vs Stim Level crosses the "t" line becomes a threshold for that group of electrodes. This threshold, referred to as the tNRI threshold, is then plotted in a second area 416 of the screen, as segment 418. The tNRI thresholds for other electrode groupings, e.g., electrodes E1-E4, E9-E12, and E13-E16 may be similarly obtained and plotted in the tNRI plot 416.

[0091] FIG. 6D shows the screen that appears when the "Macro" options is selected from the options window 412 (FIG. 6B). Selecting "Macro" allows one to run predefined values (or enter new value sets, monitor the data collection or recall previous collected data and re-run with the same stimulation parameters). For example, an OR (operating room) macro may be selected by selecting the OR macro area 420. Alternatively, a new macro may be created by selecting the "Create New Macro" area 422. Existing macros available for use are listed in the NRI Macro List window 424.

[0094] The tNRI values shown in FIG. 6F may be further processed to "smooth" the curve, particularly at the discontinuities at the boundaries between the electrode groups. Such further processing may take many forms. For example, a three-point weighted average could be used, with the first and last data points of [[a]] three-consecutive data points being weighted 25%, and the middle data point being weighted 50%. Alternatively, a b-spleen interpolation technique could be used, as could any other curve-smoothing technique known in the art.

[0096] FIG. 6G shows an example of a possible display of the data collected by the algorithm of the present invention. By selecting the "group" that was stimulated together, one can see how the tNRI was computed form the input/output function, and/or the user can inspect waveforms, as well as de-select waveforms from the computation.

[0098] Once an appropriate tNRI value is determined in accordance with the techniques described above, or in accordance with one of the other ways described in the referenced patents and patent applications, such value may be stored and saved for use during the initial turn-on of the implant device; or such value may be recommended for programming into a working implant device, or such value may be automatically programmed into a working implant device. One of the advantages of the present ~~invention~~ approach --of using ECAP values to determine the tNRI values-- is that it can be performed quickly, and in many cases automatically. Thus, it need not be limited to use only in the OR in order to find appropriate initial tNRI values. Rather, the present ~~invention~~ approach, as well as the stapedial reflex invention described in the referenced co-pending patent application (Serial No. 60/412,533, filed 09/20/2002), can be used anytime that the implant device needs to be reprogrammed, or that stimulation levels need to be adjusted, or that the neural response derived contour needs to be shifted.

[0099] As described above, it is thus seen that the present ~~invention~~ specification provides an improved system and method of fitting a neurostimulator device by measuring the ECAP of the patient through application of multi-band (i.e., multi-electrode contact) stimulation in order to better determine appropriate intensity threshold levels used by the implant system during its operation.

[0100] It is further seen that the ~~invention~~ specification provides such an improved system and method of fitting that does not require subjective feedback from the patient during the fitting procedure.

[0101] Moreover, it is seen that the ~~invention~~ specification provides a way to validate proper operation of the implant device at a time shortly after the device is implanted at a time when the patient may still be under the influence of an anesthesia, and hence unconscious.

[0102] While the ~~invention~~ techniques herein disclosed [[has]] have been described by means of specific embodiments and applications thereof, numerous modifications and variations could be made thereto by those skilled in the art without departing from the scope of the invention set forth in the claims.